IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CHRISTOPHER TYLER LOFTON, Individually and on behalf of the ESTATE of CHRISTOPHER M. LOFTON, et al., **Plaintiffs,** **v.** **MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON,** **Defendants.**	**Civil Action No. 3:05-CV-1531-L** **ECF**

DEFENDANTS' BRIEF IN SUPPORT OF
SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 30, 2010, I electronically filed the foregoing document with the clerk for the United States District Court for the Northern District of Texas, using the electronic case filing system of the Court. The electronic case filing system sent a "Notice of Electronic Filing" to all attorneys of record.

I further certify that I have served the foregoing document via certified mail, return receipt requested, to the following individuals: Ted B. Lyon, Ted B. Lyon & Associates, Town East Tower, Suite 525, 18601 LBJ Freeway, Mesquite, Texas 75150-5632.

/s/ Robert K. Mitchell
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I.

INTRODUCTION

As the Court is aware, this is a products liability case. Plaintiffs contend that Christopher Lofton's use of over-the-counter Motrin caused an extremely rare skin disorder, known as Stevens-Johnson syndrome ("SJS") or Toxic Epidermal Necrolysis ("TEN"), which resulted in his death.

On January 27, 2010, the Court entered an Order granting Defendants' Motion for Summary Judgment in part (the "Order").[1] The only remaining issues are the wrongful death and survival claims of Mr. Lofton's children for defective design and breach of implied

[1] Jan. 27, 2010 Mem. Op. and Order at 30 (App. 32) (dismissing Plaintiffs' claims for marketing defect, breach of express warranty, negligence, and violations of the Texas Deceptive Trade Practices Act, and Sandy Lofton's wrongful death and survival claims).

warranty.[2] These claims are premised on Plaintiffs' expert Randall Tackett's theory that dexibuprofen was an available, safer alternative design to Motrin at the time of Christopher Lofton's use in May 2000.[3]

As shown below, Tackett's opinion ignores the fact that dexibuprofen has never been approved for sale in the United States, and most importantly for purposes of this motion, it was not approved for, and not available for sale, in May 2000. Accordingly, it is not an available "alternative design" upon which Plaintiffs may base their claims. Moreover, under Texas law, even if dexibuprofen were available it would not be an alternative design, as it is a different drug.

Under the facts of this case, Plaintiffs (a) cannot produce the required evidence of an available safer alternative design to support their defective design and breach of implied warranty claims, and (b) failed to provide Defendants with the required notice of their implied warranty claim before filing suit. Therefore, Defendants respectfully ask this Court to dismiss Plaintiffs' remaining design defect and implied warranty claims as a matter of Texas law.

II.

SUMMARY OF ARGUMENTS

A. Defective Design

Under Texas law, a plaintiff cannot prove a design defect by claiming the defendant should have sold a different product.[4] Plaintiffs' proposed alternative design—dexibuprofen—is

[2] *Id.*

[3] In the Order, the Court ruled that: (a) Texas law recognizes Plaintiffs' design defect claim; and (b) Tackett's opinion that "pure S+ ibuprofen [found in dexibuprofen] is less likely to cause SJS or TEN than the specific mixture of R- and S+ ibuprofen in Motrin" is admissible to support Plaintiffs' design defect allegations. *Id*. at 10, 26 (App. 12, 28).

[4] *See, e.g., Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770-71 (Tex.App.—Houston [14th Dist.] 2009, no pet.).

not an "alternative" design at all, but a materially different drug with different pharmacological properties and metabolic profiles. The manufacture and marketing of dexibuprofen is neither reasonable nor feasible. Indeed, it is illegal because there has never been FDA approval; it is not *possible* to market dexibuprofen—and it was not in May 2000. FDA committees and the FDA itself were not convinced that dexibuprofen was safe enough to be marketed, and the FDA therefore did not approve a New Drug Application ("NDA") to market dexibuprofen.[5]

B. Breach of Implied Warranty

Under Texas law, Plaintiffs' claim for breach of implied warranty is predicated on their allegation that Motrin was defectively designed, and should be dismissed because the design defect claim fails. This claim should also be dismissed because Plaintiffs failed to provide Defendants with the notice required to prosecute an implied warranty claim for their alleged injuries.

III.

SUMMARY JUDGMENT MATERIALS AND EVIDENCE

Defendants rely on the following materials and evidence to support this Motion, all of which are included in the accompanying Appendix pursuant to Local Rule 56.6.

Exhibit A	Declaration of Thomas W. Pulliam, Jr. in Support of Defendants' Supplemental Motion for Summary Judgment
Exhibit B	January 27, 2010 Memorandum Opinion and Order

[5] Declaration of Steven M. Weisman, Ph.D. in Support of Supplemental Motion for Summary Judgment ("Weisman Decl.") at ¶ 10 (App. 148). The FDA's request for additional safety testing is evidence that dexibuprofen is a different product than FDA-approved ibuprofen because generic forms of the same drug do not require additional safety testing. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 n.1 (2005) ("The sponsor of a generic drug does not have to make an independent showing that the drug is safe and effective, either in preclinical or clinical studies. It need only show that the drug includes the same active ingredients as, and is bioequivalent to, the drug that it is mimicking." (citing 21 U.S.C §§ 355(j)(2)(A), (8)(B)).

Exhibit C	Excerpts from Defendants' Motion for Summary Judgment, filed May 2, 2008
Exhibit D	Plaintiffs' Second Amended Complaint
Exhibit E	Excerpts from the Declaration of Randall Tackett, Ph.D. in Support of Plaintiffs' Opposition to Defendants' Motion for Summary Judgment
Exhibit F	Excerpts from the deposition of Randall Tackett, Ph.D. taken April 4, 2008
Exhibit G	June 22, 2006 FDA Response to Citizen's Petition
Exhibit H	Defendants' Answer to Plaintiffs' Second Amended Complaint
Exhibit I	Declaration of Steven M. Weisman in Support Defendants' Supplemental Motion for Summary Judgment
Exhibit J	Curriculum Vitae of Steven M. Weisman
Exhibit K	Excerpts from the October 9, 1996 Joint FDA Committee Hearing Transcript
Exhibit L	Declaration of Anthony Temple in Support of Defendants' Supplemental Motion for Summary Judgment
Exhibit M	September 19, 1974 Approval of New Drug Application for Motrin Prescription Tablets
Exhibit N	April 15, 1983 New Drug Application for over-the-counter Motrin Ibuprofen Tablets
Exhibit O	May 18, 1984 Approval of New Drug Application for over-the-counter Motrin Ibuprofen tablets

IV.

FACTUAL BACKGROUND

A. Case History[6]

Plaintiffs' Second Amended Complaint, filed on February 15, 2006, alleges that Christopher Lofton's use of Motrin in May 2000 led to the development of SJS/TEN and caused his death on June 3, 2000. Plaintiffs asserted claims for: (a) defective design, (b) marketing

[6] For the sake of brevity, Defendants incorporate by reference the fact section of Defendants' Motion for Summary Judgment filed May 2, 2008, pp. 5-17 (App. 35-47).

defect, (c) breach of express warranty, (d) breach of implied warranty, (e) negligence, and (f) Texas Deceptive Trade Practices Act violations. Plaintiffs based their claims on allegations that Defendants defectively marketed Motrin by not adequately warning of the risk of SJS/TEN from use of the product,[7] made false and misleading statements to promote Motrin,[8] and defectively designed the product.[9]

Defendants filed a motion for summary judgment on May 2, 2008; Plaintiffs responded on May 29, 2008. While the motion was pending, on July 30, 2008, the Court administratively closed this case pending United States Supreme Court decision of relevant preemption issues in *Wyeth v. Levine*.[10] The *Levine* opinion was issued in March 2009.[11] This case was re-opened on July 30, 2009.

The Court's January 27, 2010 Order granted Defendants' summary judgment motion in part, dismissing Plaintiffs' claims for marketing defect, breach of express warranty, negligence, and violations of the Texas Deceptive Trade Practices Act, as well as Sandy Lofton's wrongful death and survival claims.[12] But drawing a distinction between prescription drugs and OTC drugs, the Court declined to apply the "unavoidably unsafe product" exception from comment k of the Restatement (Second) of Torts § 402A to OTC drugs.[13] The Court also upheld the magistrate judge's ruling that Tackett's unpublished safer alternative design theory is admissible,

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[7] Pls' Second Am. Compl. at ¶¶ 4.3, 4.4, 4.6, 4.8, 4.9 (App. 52-55).

[8] *Id.* at ¶ 4.12 (App. 55-56).

[9] *Id.* at ¶ 4 (App. 52).

[10] 552 U.S. 1161 (2008).

[11] *Wyeth v. Levine*, 555 U.S. __, 129 S. Ct. 1187 (2009).

[12] Jan. 27, 2010 Mem. Op. and Order at 30 (App. 32).

[13] *Id.* at 25-26 (App. 27-28).

and ruled that Plaintiffs' implied warranty claim remains for trial.[14] Thus, the only issues remaining before this Court are the wrongful death and survival claims of Mr. Lofton's children for defective design and breach of implied warranty.[15] Plaintiffs' sole evidence of a safer alternative design is the testimony of expert witness Randall Tackett. Tackett is a pharmacologist and toxicologist, not a medical doctor.[16]

B. Motrin's Design Is FDA-Approved for OTC Use

The FDA approved Motrin for OTC use in 1984.[17] Motrin's active ingredient is ibuprofen, a propionic acid non-steroidal anti-inflammatory drug ("NSAID").[18] The ibuprofen contained in Motrin is the only form of ibuprofen approved for use, and the only form of ibuprofen sold, in the United States.[19] Motrin is a widely used drug, available in both prescription and OTC forms.[20] Since its introduction to the market in 1967, billions of doses of ibuprofen have been sold worldwide.[21] In fact, since at least 1992, U.S. consumers alone have purchased more than 6 billion ibuprofen doses annually—which does not even include the millions of doses provided by doctors and hospitals to patients each year.[22]

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[14] *Id.* at 10, 30 (App. 12, 32).

[15] *Id.* at 30 (App. 32).

[16] Declaration of Randall Tackett In Support of Plaintiffs' Opposition to Motion for Summary Judgment ("Tackett Decl.") at ¶ 2 (App. 63-64).

[17] *See* Declaration of Anthony R. Temple, M.D. in Support of Motion for Supplemental Summary Judgment ("Temple Decl.") at ¶ 5 (App. 180); May 18, 1984 FDA approval letter (App. 190).

[18] Temple Decl. at ¶ 3 (App. 180).

[19] *Id.* at ¶ 7 (App. 181).

[20] *Id.* at ¶¶ 3-6 (App. 180-181).

[21] *Id.* at ¶ 6 (App. 181).

[22] *Id.*

C. The Record Regarding Plaintiffs' Design Defect Claim

Plaintiffs allege that Motrin was defectively designed because "the drug contained the racemic mixture of S+ and R- ibuprofen, rendering it more toxic that [sic] the alternative design well known to defendants, called dexibuprofen."[23] Plaintiffs further claim dexibuprofen would have prevented or reduced the risk of decedent's injury and death, and was economically and technologically feasible.[24]

Plaintiffs' claim for design defect is based solely on Tackett's theory. As a matter of law, his opinion is insufficient to support this claim.

1. Dexibuprofen and Ibuprofen Are Different Drugs

Dexibuprofen is not an alternative design to ibuprofen. It is a different drug that is not FDA-approved for OTC or prescription use.[25] Like many drugs, ibuprofen is a racemic mixture of two enantiomers, R- and S+ ibuprofen.[26] As Tackett explained: "[t]he two enantiomers of ibuprofen *are . . . different in terms of their pharmacological properties and may be regarded as two different drugs. They also differ in terms of their metabolic profiles. Both enantiomers are*

[23] Pls' Second Am. Compl. at ¶ 4 (App. 52).

[24] *Id*. at ¶ 4.2 (App. 52). Plaintiffs' claim for design defect includes allegations Defendants failed to: (a) adequately test Motrin for OTC use before seeking FDA approval; (b) conduct a large enough clinical trial to test for SJS/TEN; (c) adequately and completely report clinical trial data regarding the drug's risks; and (d) suppressed and diluted evidence of skin reaction, including SJS, and did not report them to the FDA or healthcare community. *Id*. at ¶ 4.1 (App. 52). As discussed, *infra* p. 9, these allegations are irrelevant to the showing required to prevail on a design defect claim.

[25] *See* Weisman Decl. at ¶ 4 (App. 147).

[26] Tackett Decl. at ¶ 149 (App. 69-70). Tackett elaborated: "[T]wo stereochemical structures depicted (the R and S symbols) are related as non-superimposable mirror images, and are identical in all respects except that one form is dextrorotary while one is levorotary. However, both forms have equal magnitude of rotation. This phenomenon is enantiomerism and each of the stereoisomers is called an enantiomer." *Id.* (App. 69).

pharmacologically active."[27] Dexibuprofen, on the other hand, only contains one enantiomer—the S compound.[28]

Tackett agrees that ibuprofen and dexibuprofen work differently: "Dexibuprofen will bind differently than a racemic mixture of Ibuprofen."[29] And he agrees the two drugs have different chemical compositions: "[dexibuprofen is] a more pure compound than the Ibuprofen."[30]

2. The FDA Has Never Approved Dexibuprofen for Use

The FDA has never approved dexibuprofen for marketing.[31] FDA committees and the FDA considered an application but were not convinced that dexibuprofen was sufficiently safe to be marketed, and accordingly, the FDA did not approve an NDA to market dexibuprofen.[32]

3. Dexibuprofen Is Neither Technologically nor Economically Feasible as an Alternative to Motrin

The record does not support Tackett's conclusion that "a safer alternative design was

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[27] *Id.* at ¶ 149 (App. 69-70) (emphasis added).

[28] *See id.* at ¶ 153 ("[dexibuprofen is] an enantiomerically pure preparation of the S-enantiomer") (App. 71); Deposition of Randall ("Tackett Dep.") at 233:6-8 (dexibuprofen is a "racemically pure compound") (App. 100).

[29] Tackett Dep. at 230:13-14 (App. 100).

[30] *Id.* at 230:19-20 (App. 100); *see also id.* at 222:9-223:7 (App. 98) ("[T]here are unique structural differences between each . . . NSAID[] that give them specific properties which . . . would explain why you would have differing effects between different NSAIDs."); *id.* at 231:18-22 (App. 100) ("[T]here's a number of papers that are out that talk about the altered metabolism of the racemic mixture, which you don't get with the Dexibuprofen."); Tackett Decl. at ¶ 155 (App. 71-72).

[31] Weisman Decl. at ¶¶ 4, 10, 11 (App. 147-148); *see also* Joint FDA Committee Hearing Transcript at 292:4-293:24 (App. 175-176) (declining to approve an application to market OTC dexibuprofen).

[32] Weisman Decl. at ¶ 10 (App. 148); Joint FDA Committee Hearing Transcript at 292:10-15, 293:8-15, and 294:11-25 (App. 175-177) (citing safety concerns and the lack of history of dexibuprofen on an OTC market anywhere in the world or a long history of it as a prescription drug—including *no history* in the United States).

scientifically and technologically feasible, and affordable to these defendants to use in order to provide a safer alternative design to Motrin, racemic ibuprofen, by designing and marketing dexibuprofen."[33] The fact that dexibuprofen is registered and marketed as a prescription drug in foreign countries[34] does not change the fact that it has never been approved by the FDA for sale in the United States, as an alternative to ibuprofen or otherwise. Thus, dexibuprofen has never been available for marketing or sale in the United States.[35] Most importantly, it was not available for marketing in the United States in May 2000, which is the relevant date for determining the existence of an available, safer alternative design.

V.

ARGUMENTS AND AUTHORITIES

A. Plaintiffs' Design Defect Claim Fails Because Dexibuprofen Is Not a Safer Alternative Design to Motrin.

To defeat a motion for summary judgment on a design defect claim, a plaintiff must, among other things, offer legally sufficient evidence to create a question of fact that: (1) there was a safer, alternative design; and (2) the safer, alternative design was available, *i.e.*, technologically and economically feasible at the time it left the manufacturer's control—here, prior to May 2000.[36] Plaintiffs lack the necessary evidence to meet these threshold requirements.

1. Dexibuprofen Is Not an "Alternative" Design

Plaintiffs cannot prevail on their defective design theory by arguing that Defendants

[33] Tackett Decl. at ¶ 159 (App. 73-74).

[34] *See id.* at ¶ 157 (App. 72-73) (citing European countries that have approved dexibuprofen for prescription use).

[35] *See id.*; Weisman Decl. at ¶¶ 10-11 (App. 148).

[36] *See Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 (Tex. 1998); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 383-84 (Tex. 1995).

should have transformed ibuprofen into another product—dexibuprofen. Dexibuprofen is not an alternative design for ibuprofen. It is a different product. The Texas Supreme Court has held that a plaintiff cannot prove a design defect by claiming that a defendant should have sold what amounts to a different product.[37]

In *Caterpillar*, the Texas Supreme Court rejected the plaintiff's argument that the defendant should have manufactured a front-end loader with a removable rollover-protective structure ("ROPS") so the ROPS was not removable. The court reasoned the plaintiff's argument would have essentially transformed the machine into a different product.

The *Caterpillar* Court explained:

> A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle. A convertible can be made safer by fully enclosing the cab, but then it is just an ordinary car. The law of products liability demands that manufacturers and distributors take feasible steps to make their products reasonably safe. It is not rational, however, to impose liability in such a way as to eliminate whole categories of useful products from the market.[38]

Likewise, "[t]he Fifth Circuit has found that a plaintiff cannot prove that a safer alternative design exists by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product."[39]

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[37] *Caterpillar*, 911 S.W.2d at 384-85 (plaintiff cannot prove design defect by claiming a defendant should have sold an entirely different product); *Brockert*, 287 S.W.3d at 770 (plaintiffs' design defect claim not viable under Texas law where a drug's proposed safer alternative design was a different product) (citing *Caterpillar*).

[38] *Caterpillar*, 287 S.W.3d at 385; *see also Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 433, n.10 (Tex. 2007) (dismissal of design defect claims was proper because there was no safer alternative design for cigarettes; "[c]ategorical liability is not only an unworkable solution, but also a position repeatedly rejected by courts.") (citations omitted).

[39] *Brockert*, 287 S.W.3d at 770 (citing *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255-56 (5th Cir. 1999) (applying Louisiana law)). Notably, the proof required to support a safer alternative design theory under Louisiana law is "very similar" to Texas law. *Smith v. Louisville Ladder Co.*, 237 F.3d 515, 519-20 (5th Cir. 2001).

In *Brockert v. Wyeth*, the Fourteenth Court of Appeals applied this reasoning to a pharmaceutical case involving the allegedly defective design of Prempro, a hormone-replacement therapy drug. Like the Plaintiffs in this case, Brockert argued that a pure drug product (estrogen) was a safer design for Prempro, which contains a combination of estrogen and progestin.[40] *Brockert* held that the plaintiff's expert testimony arguing for the pure-estrogen formula was not evidence of a safer alternative design.[41] *Brockert* recognized that under *Caterpillar*, this testimony (like Tackett's) did not support a defective design theory, but impermissibly sought to require Wyeth to sell a different product.[42] And this recognition that changing the formula transforms the drug is consistent with the fundamental principle of pharmacology and toxicology that even minor differences in the composition and structure of a chemical compound can substantially change its pharmacologic properties.[43]

Thus, a safer alternative design must affect the product at issue—here, ibuprofen—but not change it into a different product.[44] Tackett's testimony shows dexibuprofen is not a safer design for ibuprofen—it is a different formula for a different drug. Nowhere does Tackett explain how ibuprofen could be modified or improved; instead he opines that the FDA-approved two-enantiomer ibuprofen compound should instead be a one-enantiomer dexibuprofen formula that the FDA did not approve. The fact that the FDA did not approve dexibuprofen for marketing (neither OTC nor by prescription), but has approved the marketing of ibuprofen (both

[40] *Brockert*, 287 S.W.3d at 669.

[41] *Id*. at 770.

[42] *Id*. at 770-71.

[43] *See, e.g., Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2006) ("Even minor differences in chemical structure can radically change a particular substance's properties and propensities.").

OTC and by prescription) makes plain that these are considered different drugs.[45]

In sum, the record shows:

> • Ibuprofen is a racemic mixture that contains two enantiomers, R- and S+ ibuprofen.[46]
>
> • "[T]he two enantiomers of ibuprofen *are . . . different in terms of their pharmacological properties and may be regarded as two different drugs. They also differ in terms of their metabolic profiles. Both enantiomers are pharmacologically active*."[47]
>
> • "Dexibuprofen will bind differently than a racemic mixture or ibuprofen," and is "a more pure compound than the Ibuprofen."[48]
>
> • "[T]here are unique structural differences between each . . . NSAID[] that give them specific properties which may mean — which would explain why you would have differing effects between different NSAIDs."[49]
>
> • The FDA views the two as different drugs; it has approved ibuprofen for OTC and prescription use,[50] but has not approved dexibuprofen for use.[51]

In other words, dexibuprofen is not an alternative design for ibuprofen, but a different drug product.

"[A]s the supreme court has explained, Texas law does not recognize this sort of

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[44] *See Brockert*, 287 S.W.3d at 770.

[45] *See Merck KGaA*, 545 U.S. at 196 n.1; *see also* 21 U.S.C. § 355 (j)(2)(A).

[46] Tackett Decl. at ¶ 149 (App. 69-70).

[47] *Id.* (emphasis added).

[48] Tackett Dep. at 230:13-14 (App. 100).

[49] *Id.* at 222:9-223:7 (App. 98).

[50] Temple Decl. at ¶¶ 3, 5, 7 (App. 180-181).

[51] Weisman Decl. at ¶ 4 (App. 147).

categorical attack on a product."[52] Moreover, "the range of consumer choice among products are factors that may be taken into account" in alternative design cases.[53] Notable here, the FDA responded to a Citizen's Petition asking it to modify the labeling of NSAID drugs (including OTC ibuprofen) by emphasizing the public health importance of maintaining "a *range of options* in the NSAID class from which physicians and patients may choose."[54] The FDA declined to remove OTC ibuprofen products from the marketplace. Instead, it stated that the "overall benefit versus risk profile" for ibuprofen products remained "very favorable."[55]

Therefore, Plaintiffs' defective design claim fails.

2. There Is No Evidence that Dexibuprofen Was a Technologically and Economically Feasible Alternative to Ibuprofen.

Whether a product has a design defect is evaluated "in light of the economic and scientific feasibility of safer alternatives."[56] The degree of feasibility is one factor courts weigh in balancing the utility of a product against its risks.[57]

As a matter of law, dexibuprofen cannot constitute a technologically and economically feasible alternative. When proving the existence of a reasonable alternative design, the drug must first be *available*. Dexibuprofen is not available. More importantly, it was not available in May 2000.

Dexibuprofen is not simply a redesign of ibuprofen, but a different, foreign drug product

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[52] *See Brockert*, 287 S.W.3d at 771.

[53] *Uniroyal Goodrich Tire Co.*, 977 S.W.2d at 335 (quoting the Restatement (Third) of Torts: Product Liability § 2 cmt. f).

[54] June 22, 2006 FDA Response to Citizens' Petition at 2 (App. 105) (emphasis added).

[55] *Id.* at 9 (App. 112).

[56] *Caterpillar*, 911 S.W.2d at 384.

[57] *Id.*

that is *neither marketed nor approved* for marketing (OTC or prescription) in this country. The FDA did not approve an application to market the design submitted in 1996. Plaintiffs' design-defect argument completely ignores the requirement that all drugs sold in the United States must first have FDA approval.[58] Because the FDA did not approve the request for approval of dexibuprofen,[59] it was not an *available* design in May 2000.[60] The ibuprofen contained in Motrin is the only form of ibuprofen approved for use, and the only form of ibuprofen that may be sold, in the United States.[61] And that was true in May 2000.

"Whether a product was defective must be judged against the technological context existing at the time of its manufacture."[62] Plaintiffs have made absolutely no showing as to the technological feasibility of manufacturing and marketing dexibuprofen in May 2000, or at any time. Nor could they, because the simple fact is that it *could not be marketed* in the United States in May 2000. As a matter of law, it cannot be considered an available, safer alternative design, and cannot support a design defect claim.

B. Plaintiffs' Claim for Breach of Implied Warranty Is Predicated on Their Defective Design Claim and Should Also Be Dismissed.

1. Without Evidence of a Safer Alternative Design, Plaintiffs' Breach of Implied Warranty Claim Is Untenable.

Plaintiffs allege that Defendants impliedly warranted that Motrin was of merchantable

[58] *See* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.").

[59] *See* nn. 31-32, *supra*.

[60] *See* 21 U.S.C. § 355(a), (b).

[61] Temple Decl. at ¶ 7 (App. 181).

[62] *Nissan Motor Co. v. Armstrong*, 145 S.W.3d 131, 139 (Tex. 2004).

quality, and was safe and fit for its intended use, but it was not.[63] The Court has dismissed Plaintiffs' claims based on marketing defect and the failure to warn.[64] Thus, design defect is the only remaining basis for Plaintiffs to impose implied warranty liability.[65] If the Court dismisses Plaintiffs' design defect claims for the reasons set forth above, there will be no grounds upon which Plaintiffs' breach of implied warranty claim can proceed.[66]

Addressing this very issue under Texas law, the Fifth Circuit held that a claim for breach of implied warranty fails where the plaintiff offers insufficient evidence of a safer alternative design to support a design defect theory.[67] This is because "the issues regarding the existence of design defect and breach of warranty [are] identical."[68]

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[63] Pls' Second Am. Compl. at ¶ 4.7 (App. 54).

[64] Jan. 27, 2010 Mem. Op. and Order at 30 (App. 32).

[65] *Caterpillar*, 911 S.W.2d at 381-82 (Texas law recognizes product liability theories of manufacturing, design, or marketing defect). Plaintiffs do not allege a defect in the manufacture of Motrin.

[66] *See Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665 (Tex. 1999) (In personal injury cases, the defect required to support a strict liability claim and a breach of implied warranty claim are "functionally identical."); *see also Patterson v. Rohm Gesellschaft*, 608 F. Supp. 1206, 1211 (N.D. Tex. 1985) ("There can be no valid products liability claim without a product which has a defect."); *Otis Spunkmeyer, Inc. v. Blakely*, 30 S.W.3d 678, 690 (Tex.App.—Dallas 2000, no pet.) ("depending on the facts of each case, whether a manufacturing defect exists for purposes of products liability often resolves whether a product was defective and, therefore, breached an implied warranty of merchantability."); *Flock v. Scripto-Tokai Corp.*, Civil Action H-00-3794, 2001 U.S. Dist. LEXIS 23878, at *62 (S.D. Tex. Nov. 19, 2001) ("To the extent that [Plaintiffs' breach of warranty] claims are based on theories of marketing and/or manufacturing defects, however, they are foreclosed, as Plaintiffs have not demonstrated the existence of such alleged defects in the products."); *Foster v. Ford Motor Co.*, 621 F.2d 715, 719-20 (5th Cir. 1980) (under Texas law, elements for breach of implied warranty and strict liability are substantially similar; plaintiff not entitled to breach of warranty instruction).

[67] *Smith*, 237 F.3d at 521 ("In sum, because Smith failed to establish a safer alternative design for the ladder in use at the time of the accident, his claim predicated on breach of implied warranty must fail, along with his design defect claim.").

[68] *Id.* at 521 (citing *Hyundai Motor Co.*, 995 S.W.2d at 667). *See also Flock v. Scripto-Tokai Corp.*, 183 F. Supp. 2d 917, 920-21 (S.D. Tex. 2001) ("The warranty claims require the same evidence of causation as the product liability claims. They are thus untenable.") (citations omitted).

2. Plaintiffs' Failure to Provide Timely Notice of Breach Is Fatal to Their Implied Warranty Claim.

In Texas, "a buyer, upon accepting tender, must notify the seller of any breach 'within a reasonable time after he discovers any breach . . . or be barred from any remedy.'"[69] As Texas courts have recognized, the "pre-suit notice requirement is condition precedent" to recover under a breach of implied warranty theory.[70] Plaintiffs bear the burden to plead and prove timely notice.[71]

There is no evidence that Plaintiffs supplied Defendants with notice of any alleged breach of warranty before filing suit.[72] Because "there is no room for ordinary minds to differ" regarding Plaintiffs' failure to satisfy the statutory notice requirement, Plaintiffs' claim for breach of implied warranty fails as a matter of law for this additional reason.[73]

VI.

CONCLUSION

For these reasons, Defendants respectfully request that this Court grant Defendants' Supplemental Motion for Summary Judgment, and enter judgment in Defendants' favor.

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[69] *Palmco Corp. v. Am. Airlines*, 983 F.2d 681, 684 (5th Cir. 1993) (quoting Tex. Bus. & Com. Code Ann. § 2.607(c)(1)); *see also Holland v. Hoffman-La Roche, Inc.*, No. 3-06-CV1298-BD, 2007 U.S. Dist. LEXIS 84507, at *8 (N.D. Tex. Nov. 15, 2007) (barring a breach of warranty claim in a personal injury pharmaceutical case because the plaintiff failed to give the drug manufacturer notice of the claim); *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 745 (E.D. Tex. 2006) (same); *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 199 (Tex. App.—Houston [1st Dist.] 2003, pet. denied).

[70] *See Holland*, 2007 U.S. Dist. LEXIS 84507 at *8 (citing *U.S. Tire-Tech*, 110 S.W.3d at 199); *Martin v. Home Depot U.S.A. Inc.*, 369 F. Supp. 2d 887, 893 (W.D. Tex. 2005).

[71] *See Holland*, 2007 U.S. Dist. LEXIS 84507 at *8 (relying on *U.S. Tire Tech* to grant summary judgment as to plaintiff's breach of warranty claim).

[72] *See* Pls' Second Am. Compl. at ¶¶ 3-4.7 (App. 50-54); *see also* Defs' Answer to Pls' Second Am. Compl. at ¶ 15 (App. 139).

[73] *Palmco Corp.*, 983 F.2d at 685 (quoting *Carroll Instr. Co. v. B.W.B. Controls*, 677 S.W.2d 654, 657 (Tex. App.—Houston [1st Dist.] 1984, no writ)).